

TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Economic Impact Statement

LSA Doc. #09-810

Description of the Rule

The proposed rule amends 410 IAC 1-4-8 (a) to update guidance documents imposing requirements of all covered individuals and health care workers. Currently the rule requires an individual who has professional, employment, or volunteer duties that require the individual to have direct contact with blood or body fluids in the scope of the individual's duties to use universal precautions. Covered individuals must comply with requirements imposed under Indiana Occupational Safety and Health Administration (OSHA) bloodborne pathogens standards (29 CFR 1910.1030). In the 20 years following the initial promulgation of the rule, the rule has not been changed. The amendment will require additional compliance to include Guideline for Hand Hygiene in Health-Care Settings Recommendations of the HICPAC/SHEA/APIC/IDSA Task Hand Hygiene Force and WHO Guidelines on Hand Hygiene in Health Care ("Hand Hygiene Guidelines"). The Hand Hygiene Guidelines are best practices which are followed by all health care workers in licensed facilities. The amendment will extend best practices to employees of covered facilities who have a professional, employment, or volunteer duties that require the individual to have direct contact with blood or body fluids in the scope of the individual's duties. Effective 30 days after filing with the Publisher.

Economic Impact on Small Businesses

- 1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.**

Indiana State Department of Health (ISDH) is unable to provide a precise estimate of the number of individuals affected by this rule. ISDH estimates the current number of individuals who have professional, employment, or volunteer duties that require the individual to have direct contact with blood or other body fluids as part of their medical, public health, or public safety duties exceeds 300,000. ISDH estimates over 20,000 facilities may be affected due to the provision of services that may include exposure to blood or other body fluids.

- 2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.**

The proposed amendment to the Universal Precautions Rule does not add any annual reporting, record keeping or other administrative costs for small businesses to comply with the rule.

- 3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.**

The proposed amendment to the Universal Precautions Rule does not increase the economic impact on small business for complying with the rule.

4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt the rule; or any other state or federal law.

The proposed amendment to the Universal Precautions Rule conforms with recommended standards as set by: Occupational Safety and Health Administration (OSHA), Centers for Disease Control (CDC), Healthcare Infection Control Practices Advisory Committee (HICPAC), Society for Healthcare Epidemiology of America (SHEA), Association for Professionals in Infection Control and Epidemiology (APIC), Infectious diseases Society of America (IDSA) and World Health Organization (WHO) and does not add any burden to facilities. Professionals should not compromise on patient safety or regulations that reduce the incidence of infections. Failure to comply with universal precautions will increase the likelihood that an individual who is exposed to blood or body fluid will acquire a dangerous communicable disease.

5. Regulatory Flexibility Analysis

Other factors considered:

A. Establishment of less stringent compliance or reporting requirements for small businesses.

The proposed amendment provides updated requirements based on best practices. Compliance with these guidance documents achieves the highest quality of patient care that serves the medical community and the public interest. Less stringent requirements would increase the likelihood that an individual exposed to blood or body fluids would acquire a dangerous communicable disease such as hepatitis B. The average annual cost of approved hepatitis B therapy is \$24,000 for a single drug. Estimated charges for liver transplantation would be \$392,800, with additional annual follow up cost of \$21,900.

B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

The proposed amendment does not change schedules or deadlines for compliance or reporting requirements.

C. Consolidation or simplification of compliance or reporting requirements for small businesses.

There are no new reporting requirements imposed by the proposed amendment to the rule.

D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.

Universal precautions are best practices for the prevention of the spread of dangerous communicable disease through contact with blood or body fluids.

E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule.

Exposure to dangerous communicable disease through blood or body fluids is a risk for small and large businesses.

Conclusion

The proposed amendment provides updated guidance documents based on best practice. Less stringent requirements would increase the likelihood that an individual exposed to blood or body fluids would acquire a dangerous communicable disease. The amendment does not require additional costs for small businesses.

Submitted by,

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